

**REMARKS/ARGUMENTS**

By this Amendment, Claims 1, 9, 21, 32, 38, 45, 60 and 61 are amended. Thus, Claims 1-70 are currently pending.

The Examiner has rejected Claims 21, 31-34, 60 and 61 under 35 U.S.C. §112, second paragraph as being indefinite and, in particular, to no antecedent basis for the term “protrusion” in Claim 21, as well as the term “barrel scale” in Claim 32. To that end, Applicants have amended Claims 21, 32, 60 and 61 to overcome this rejection.

The Examiner has rejected 1-31, 35-42, 44-65 and 69-70 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,478,316 (Bitdinger, et al., hereinafter “Bitdinger”). In particular, the Examiner asserts that the device of Bitdinger discloses all of the elements of independent Claims 1, 9, 38, 44 and 45:

...Bitdinger discloses (abstract; figures 1-19) an injection device comprising: a housing (12) having a proximate end and a distal end, the distal end (16) having an opening therein; a shield (28) slideably coupled to the housing at said distal end thereof; a cartridge barrel (30) within the housing, the cartridge barrel having proximate and distal ends; a needle cannula (38) fixed to the distal end of the cartridge barrel, or attachment means for fixing a needle cannula to the distal end, said needle cannula being disposed within said shield prior to activation of said device (figures 2-5); a stopper (24) within the cartridge barrel; a driver (32, 46) coupled to the stopper; a spring (40,56) coupled between the housing and the driver; a driver trigger (66) for retaining the driver fixed to the housing and in which state the spring is in a compressed state, the trigger being actuatable in use to release the driver from the housing thereby allowing the spring to urge the driver through the housing and with it the stopper through the cartridge barrel; and a release mechanism for releasing the spring from the driver at some point on its travel through the housing, whereupon the spring engages the shield and automatically urges the shield way from the housing so as to cover the needle cannula (column 4, 9-65). Office Action, dated July 23, 2008, pp. 2-3.

Applicants respectfully traverse the rejection for the following reasons.

As discussed in the detail on pp. 17-21 of the present application, displacement of the

shield 250 at the injection site sets into motion a completely automatic operation of the driver 400 which delivers the fluid, extends the shield 250 forward while removing the needle 512 and locks the shield in place, thereby covering the needle 512. Thus, the driver trigger is automatic: there is no need for any other operator intervention, other than to press the injector at the injection site.

In complete contrast to this, the Bitdinger device is not automatic. Pressing the Bitdinger device at the injection site does not result in the automatic delivery of fluid, shield extension, removal of needle and locking the shield in place. Rather, pressing the Bitdinger device at the injection site, only results in enabling a manual trigger 66 to be activated by the operator. In particular,

The end of the sleeve 28 is pressed against the epidermis, thereby causing a force F to be exerted thereon as shown in FIG. 5. The sleeve moves rearwardly against the force of the sleeve spring 40 for several millimeters, at which time the rear portion 44 of the sleeve engages a stop 12C extending from the housing 12. *This movement is sufficient to displace the sleeve projection 28A a sufficient distance that it no longer interferes with the downward movement of the pushbutton 66.*

*The projection 66C of the pushbutton is pressed manually towards the housing as shown in FIG. 6.* This causes displacement of the first engagement member 66A such that it no longer engages the driver 58. The driver 58 and rod 46 move as a unit under the constant force of the spring 56, causing the syringe assembly 20 (via the plug 24) to move forwardly, and the needle 38 thereof to penetrate the skin. As the rod remains coupled to the driver, the piston 32 does not move. Once the needle has sufficiently penetrated the skin and underlying tissue, the projection 64 on the driver 58 engages the projection 70 extending inwardly from the housing 12. This causes the pivotable arm 62 of the driver to rotate, and the pawl 60 to move out of the notch 52. The driver 58 and rod are decoupled at this point, which is just prior to the bottoming of the sleeve spring 40. (Bitdinger, col. 5, line 51 to col. 6, line 7).

Thus, from the foregoing, it is clear that pressing the Bitdinger device against the injection site, only clears any possible interference that the shield 28A would normally have with

the pushbutton 66. With the shield 28A displaced “out of the way”, the operator then manually must press the projection 66C of the pushbutton 66 to continue with the operation of the Bitdinger device.

Therefore, to more clearly distinguish over Bitdinger, Applicants have amended Claims 1, 9, 38, and 45 accordingly. Applicants respectfully submit that Claims 1, 9, 38 and 45 are patentable over Bitdinger and that the §102(b) should be withdrawn.

With particular regard to Claim 44, Applicants respectfully transverse the §102(b) rejection in that Bitdinger fails to disclose the use of a single spring as specified in Claim 44:

...a single spring, engaged with said driver, that is released by a user force, said single spring displacing said driver for automatically injecting and delivering the fluid into the living being and for automatically acting against the needle shield to remove the needle from the living being while automatically concealing the needle within said shield once the fluid delivery is complete.

In contrast, the Bitdinger device requires three springs to accomplish the same task, namely, a compression spring 40, a constant force spring 56 and the coil spring 68 of the pushbutton 66. All of these are required to accomplish the same result as the single spring of present invention. In fact, the device of Bitdinger requires the use of a constant force spring 56 to overcome the friction between the piston 32 and the cartridge 30 and between the needle 38 and the patient’s skin. If a coil spring was employed in the drive assembly, a steadily increasing force would be required to reload the device (Bitdinger, col. 4, lines 23-30). In contrast, the invention of the present application is able to deliver its fluid during injection without the use of any constant force spring. Thus, Applicants submit that Claim 44, as is currently pending, distinguishes over Bitdinger and they respectfully request that the §102(b) rejection also be

withdrawn against this claim.

Claim 2 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 3 is dependent upon Claim 1 and is patentable for the same reasons. Furthermore, it should be noted that movement of the shield 28A of Bitdinger does not activate the trigger 66. Rather, as explained previously, movement of the shield 28A simply removes any interference it may pose with the pushbutton trigger 66 which must be pressed manually in order to activate the trigger. (Bitdinger, col. 5, lines 56-61). Thus, Claim 3 is patentable over Bitdinger for all of these reasons.

Claim 4 is dependent upon Claim 3 and is patentable for the same reasons.

Claim 5 is dependent upon Claim 3 and is patentable for the same reasons.

Claim 6 is dependent upon Claim 1 and is patentable for the same reasons. Furthermore, there is no resilient member on one of the driver and the housing and a complimentary engaging member on the other of the driver and housing in Bitdinger. Rather, the pushbutton 66 of Bitdinger acts as the trigger. Thus, Claim 6 is patentable over Bitdinger for all of these reasons.

Claim 7 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 8 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 10 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 11 is dependent upon Claim 10 and is patentable for the same reasons. Moreover, nowhere does Bitdinger disclose a shield displacement and driver disengagement force of about 1 kgf. Thus, Claim 11 is patentable over Bitdinger for all of these reasons.

Claim 12 is dependent upon Claim 10 and is patentable for the same reasons.

Claim 13 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 14 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 15 is dependent upon Claim 14 and is patentable for the same reasons.

Claim 16 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 17 is dependent upon Claim 9 and is patentable for the same reasons. Moreover, Bitdinger does not appear to disclose any set of cartridge barrel supports that extend longitudinally and which slide on the external surface of the barrel during injection.

Claim 18 is dependent upon Claim 17 and is patentable for the same reasons. Furthermore, Bitdinger does not disclose any cartridge barrel supports that are adapted to detect the end of the barrel and release the driving unit.

Claim 19 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 20 is dependent upon Claim 19 and is patentable for the same reasons. Furthermore, Bitdinger does not discuss tactile feedback.

Claim 21 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 22 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 23 is dependent upon Claim 22 and is patentable for the same reasons.

Claim 24 is dependent upon Claim 22 and is patentable for the same reasons.

Claim 25 is dependent upon Claim 23 and is patentable for the same reasons.

Claim 26 is dependent upon Claim 9 and is patentable for the same reasons. Moreover, Bitdinger does not even mention the use of any safety tab. Thus, Claim 26 is patentable over Bitdinger for all of these reasons.

Claim 27 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 28 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 29 is dependent upon Claim 28 and is patentable for the same reasons. Furthermore, Bitdinger does not even mention the use of a leaf spring. Thus, Claim 29 is patentable over Bitdinger for all of these reasons.

Claim 30 is dependent upon Claim 28 and is patentable for the same reasons.

Claim 31 is dependent upon Claim 21 and is patentable for the same reasons.

Claim 35 is dependent upon Claim 28 and is patentable for the same reasons.

Claim 36 is dependent upon Claim 28 and is patentable for the same reasons.

Claim 37 is dependent upon Claim 33 and is patentable for the same reasons.

Claim 39 is dependent upon Claim 38 and is patentable for the same reasons. Furthermore, Bitdinger does not even mention an opening in the proximate end of the housing. As shown in all of the figures of Bitdinger, the proximate end of the device is closed. In fact, since the Bitdinger device is re-usable, the cartridge/needle is replaced at the distal end, not the proximal end, of the device. Thus, Claim 39 is patentable over Bitdinger for all of these reasons.

Claim 40 is dependent upon Claim 39 and is patentable for the same reasons.

Claim 41 is dependent upon Claim 39 and is patentable for the same reasons. Furthermore, Bitdinger does not even mention any threaded member. Thus, Claim 41 is patentable over Bitdinger for all of these reasons.

Claim 42 is dependent upon Claim 39 and is patentable for the same reasons. Furthermore, Bitdinger does not even mention any serrations. Thus, Claim 42 is patentable over Bitdinger for all of these reasons.

Claim 46 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 47 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 48 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 49 is dependent upon Claim 48 and is patentable for the same reasons.

Claim 50 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 51 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 52 is dependent upon Claim 51 and is patentable for the same reasons.

Claim 53 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 54 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 55 is dependent upon Claim 45 is patentable for the same reasons. Moreover, Bitdinger does not appear to disclose any set of cartridge barrel supports that extend longitudinally and which slide on the external surface of the barrel during injection.

Claim 56 is dependent upon Claim 55 and is patentable for the same reasons. Furthermore, Bitdinger does not disclose any cartridge barrel supports that are adapted to detect the end of the barrel and release the shield.

Claim 57 is dependent upon Claim 55 and is patentable for the same reasons.

Claim 58 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 59 is dependent upon Claim 58 and is for the same reasons. Furthermore, Bitdinger does not discuss tactile feedback.

Claim 60 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 61 is dependent upon Claim 60 and is patentable for the same reasons.

Claim 62 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 63 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 65 is dependent upon Claim 63 and is patentable for the same reasons.

Furthermore, Bitdinger does not even mention the use of a leaf spring. Thus, Claim 65 is patentable over Bitdinger for all of these reasons.

Claim 66 is dependent upon Claim 45 and is patentable for the same reasons. Moreover, Bitdinger does not even mention the use of any safety tab. Thus, Claim 66 is patentable over Bitdinger for all of these reasons.

Claim 69 is dependent upon Claim 45 and is patentable for the same reasons. As mentioned previously, Bitdinger does not even discuss the use of any safety tab. Thus, Claim 69 is patentable over Bitdinger for all of these reasons.

Claim 70 is dependent upon Claim 45 and is patentable for the same reasons.

The Examiner has rejected 32-34, 43 and 67-68 under 35 U.S.C. §103(a) as being unpatentable over Bitdinger in view of U.S. Patent No. 5,599,309 (Marshall, et al., hereinafter "Marshall"). In particular, the Examiner asserts that the device of Bitdinger discloses all of the elements of these claims except for the housing and shield including a window arranged for viewing of the barrel, barrel scale and fluid in the barrel. To make up for that deficiency, the Examiner cites Marshall as including these features and then asserts that it would have been obvious to one skilled in the art to modify the device of Bitdinger as disclosed in Marshall to arrive at the claimed inventions.

Applicants respectfully traverse this rejection for the following reasons.

Nowhere in Marshall is there any disclosure of a window, let alone a window for viewing a barrel, a barrel scale or fluid in the barrel. Thus, Claims 32-34, 43 and 67-68 are patentable over the cited art and Applicants request that the §103(a) rejection be withdrawn.

The Examiner has maintained the rejection of Claims 1, 9, 38, 44 and 45 under 35 U.S.C. §103(a) as already being unpatentable over U.S. Patent Publication No. 2002/0193746 (Chevallier) and/or U.S. Patent No. 6,319,233 (Jansen) in view of U.S. Patent No. 7,097,634 (Gilbert). Although the Examiner has stated that Applicants' argument of April 28, 2008 have been fully considered and are not persuasive, the Examiner has repeated the exact wording of the Nov. 2, 2007 Final Rejection. The only change that the Examiner has made is to assert that "Gilbert discloses (column 1, lines 20-50) the cannula being disposed within said shield prior to activation of said device and further discloses the syringe is automated." However, such a statement fails to address the following arguments previously presented by Applicants:

1. Chevallier and Gilbert

Even if one skilled in the art were to combine Chevallier and Gilbert as suggested by the Examiner, the result would still not disclose the inventions of Claims 1, 9, 38, 44 and 45 because the needle of that Chevallier/Gilbert combination would still be exposed after injection, as clearly shown in Fig. 6 of Gilbert which contravenes the final elements of Claims 1, 9, 38, 44 and 45:

...a release mechanism for releasing the spring from the driver at some point on its travel through the housing, whereupon the spring engages the shield and automatically urges the shield away from the housing so as to cover the needle cannula. (Claim 1);

...wherein said shield is automatically deployed following fluid delivery so as to cover the needle. (Claim 9);

wherein said shield is automatically deployed following fluid delivery so as to cover the needle. (Claim 38);

...while automatically concealing the needle within said shield once the fluid delivery is complete. (Claim 44); and

...wherein said shield is automatically deployed following fluid delivery so as to cover the needle. (Claim 45).

## 2. Jansen and Gilbert

Even if one skilled in the art were to combine Jansen and Gilbert as suggested by the Examiner, the result would still not disclose the inventions of Claims 1, 9, 38, 44 and 45 because the needle of that Jansen/Gilbert combination would still be exposed after injection, as clearly shown in Fig. 6 of Gilbert which contravenes the final elements of Claims 1, 9, 38, 44 and 45 discussed previously with regard to the Chevallier/Gilbert combination.

Applicants submit that these arguments are directed at the Examiner's suggested combination of the Chevallier/Gilbert references, and the Jansen/Gilbert references, and that such combinations do not teach nor suggest the invention of Claims 1, 9, 38, 44 or 45. The Examiner fails to show where the combination of Chevallier/Gilbert, or Jansen/Gilbert, teach or suggest the automatic deployment of a shield to conceal the needle following injection. Thus, as detailed in the previous response, Applicants submit that there is no suggestion to combine the teachings and suggestions of Chevallier and Gilbert, nor Jansen and Gilbert, as advanced by the Examiner, except by using Applicants' invention as a template through hindsight reconstruction of the pending claims. Furthermore, even if one skilled in the art were to combine Chevallier and Gilbert, or to combine Jansen and Gilbert, the result would still be an exposed needle after the injection, as shown by Fig. 6 of Gilbert. Applicants therefore respectfully submit that the invention of Claims 1, 9, 38, 44 and 45 are patentable over any proposed combination of Chevallier and Gilbert, or Jansen and Gilbert, and respectfully request that the §103(a) rejection based thereon be removed.

The Examiner has maintained the rejection of Claims 2, 3-7, 8, 10-15, 35-37, 46-48, 61, 63-64, 70, 19-21, 50-52 and 58-59 under 35 U.S.C. §103(a) as being unpatentable over Chevallier and/or Jansen in view of U.S. Patent Publication No. 2003/01005430 (Lavi, et al.) and/or U.S. Patent No. 5,599,309 (Marshall) and further in view of Gilbert.

Applicants respectfully disagree for the following reasons.

Claims 2, 3-7, 8, 10-15, 35-37, 46-48, 61, 63-64, 70, 19-21, 50-52 and 58-59 ultimately depend from Claims 1, 9, 38, 44 and 45 accordingly and are therefore patentable for the same reasons. In view of the foregoing, Applicants respectfully submit that Claims 2, 3-7, 8, 10-15, 35-37, 46-48, 61, 63-64, 70, 19-21, 50-52 and 58-59 are patentable over the art of record and respectfully request that the §103(a) rejection be withdrawn.

Thus, Applicants respectfully submit that Claims 1-70 are now in condition for allowance. Accordingly, prompt and favorable examination on the merits is respectfully requested.

Application Serial No. 10/566,333  
Attorney Docket No. S2082/20004  
Amendment Dated October 20, 2008

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for initial examination and allowance, the Examiner is invited to contact Applicant's undersigned attorney at the telephone number listed below.

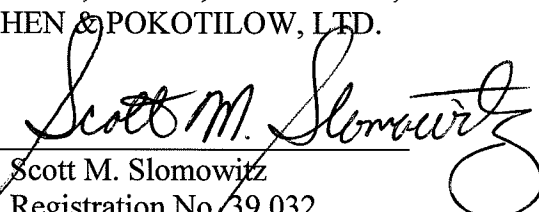
Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOW, LTD.

October 20, 2008

Please charge or credit our  
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By

  
Scott M. Slomowitz

Registration No. 39,032

Customer No. 03000

(215) 567-2010

Attorneys for Applicants